REMARKS

I. PRELIMINARY REMARKS

Claims 7, 28, 43 and 47 have been amended. Claims 48-53 have been canceled. No claims have been added. Claims 7-12, 28-35, 37-40 and 43-47 remain in the application. Claims 12 and 29 have been withdrawn from consideration. Reexamination and reconsideration of the application, as amended, are respectfully requested.

II. BRIEF DESCRIPTION OF EXEMPLARY EMBODIMENTS

The present inventions, as defined by the claims, are directed generally to surgical systems and apparatus that may be used to stimulate tissue. Referring to Figures 29-32, the exemplary stimulation and sensing probe 616 includes a suction device 618 that carries one or more tissue stimulation elements 604. Such stimulation elements 604 may be for tissue stimulation, and to sense electrical activity in tissue. [Specification at, for example, page 37, line 21 to page 38, line 3.] The tissue stimulation elements 604 are also too small to form a transmural lesion in myocardial tissue. [Specification at, for example, page 34, lines 17-23 and page 29, lines 21-33.] The suction device 618 illustrated in Figures 29-32 is also devoid of any apparatus that is capable of forming a transmural lesion in myocardial tissue.

III. REJECTION UNDER 35 U.S.C. § 112

A. The Rejection

Claims 7-11, 28, 30-35 and 37-40 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the enablement requirement. More specifically, the basis for the rejection appears to be that (1) the present specification did not provide the "threshold size" at which a stimulation element will not be able to

form a transmural myocardial lesion and (2) there are stimulation elements that are not capable of forming a transmural lesion in myocardial tissue in one "modality," but are capable of forming a transmural lesion in myocardial tissue in another.[1] The Office Action appears to at least partially base the non-enablement conclusion on a portion of the present application that is directed to a non-elected surgical probe-related invention as well as the teachings of U.S. Patent No. 5,687,723 to Avitall ("the Avitall patent") and U.S. Patent No. 5,406,946 to Imran ("the Imran patent").

The rejection under 35 U.S.C. § 112, first paragraph, is respectfully traversed. Reconsideration thereof is respectfully requested.

B. Discussion

The test for determining whether or not an application meets the enablement requirement is, quite simply, whether or not the application enables a person skilled in the art to ***make and use*** the ***claimed invention*** without undue experimentation. [MPEP § 2164.01.]

The first step in determining whether or not the enablement requirement has been met is determining what is being claimed. Applicant notes for the record that the present application was subject to an election of species requirement. Applicant elected Species 8 and Subspecies A, examples of which are illustrated in Figures 29 and 31. Referring to the exemplary embodiment illustrated in Figure 31, the elected invention includes, *inter alia*, "***a suction device***" and "***a tissue stimulation element*** that is too small to form a transmural lesion in myocardial tissue ***on the suction device***." The Examiner's attention is directed to the suction device 618 and the stimulation electrode 604 of the exemplary embodiment. To summarize, what is being claimed includes (1) a suction device

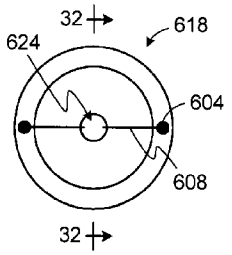


FIG. 31

[1] Applicant notes for the record that although the explanation of the rejection makes reference to "means," there are no means-plus-function elements in the rejected claims.

and (2) a tissue stimulation element on the suction device that is too small to form a transmural lesion in myocardial tissue. If, in the Examiner's opinion, something else is being claimed, applicant hereby respectfully requests that the next Office Action say so in order to clarify the issues for appeal.

Moving beyond the issue of "what is being claimed" to the issue of whether or not the application provides enough information to enable a person skilled in the art to ***make and use*** the ***claimed*** invention, the present application provides specific examples of ***stimulation elements*** that are ***on a suction device*** and are too small to form a transmural myocardial lesion. The description of these examples includes size, shape and material information, as well as specific examples of how such stimulation elements may be made:

> In the exemplary implementations illustrated in Figures 25-32, the stimulation electrodes 604 are essentially the same as the stimulation and sensing electrodes 426 and 428 described above. For example, the electrodes 604 may be relatively small, low profile devices (e.g. about 0.5 mm to 1 mm in diameter and about 0.01 mm thick) that can be formed by coating one of the suitable conductive materials described above onto the tissue engagement device 602.

[Specification at page 34, lines 17-23.] In order to assist the Examiner, and to the extent that there is confusion concerning what the exemplary stimulation electrodes 604 actually look like, Figures 31 and 32 are reproduced below. They are the small, dot-like objects on the distal surface of the suction device 618.

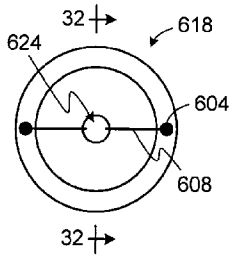


FIG. 31

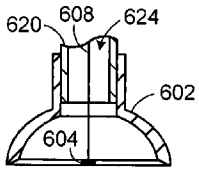


FIG. 32

With respect to the stimulation and sensing electrodes 426 and 428, which the above-quoted portion of the specification refers to as being "essentially the same as" the stimulation electrodes 604, the specification states:

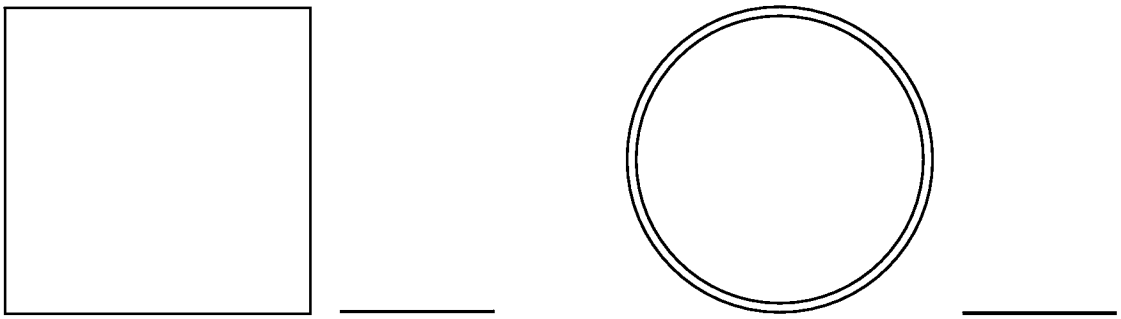
> [T]he exemplary tissue stimulation and sensing electrodes 426 and 428 may be relatively small (i.e. ***too small to form transmural myocardial lesions***), low profile devices. Suitable sizes are about 0.5 mm to 1 mm in diameter, and a suitable thickness is about 0.01 mm. Such electrodes may be formed by coating a conductive material onto the suction device 404 using conventional coating techniques or an IBAD process. Suitable conductive materials include platinum-iridium and gold. An undercoating of nickel, silver or titanium may be applied to improve adherence. Conductive ink compounds, such as silver-based flexible adhesive conductive ink (polyurethane binder) or metal-based adhesive conductive inks (e.g. platinum, gold, or copper based) may also be pad printed onto the suction device 404.

[Page 29, lines 21-33.] The present application also discloses how to use this aspect of the claimed inventions. [See, *e.g.*, page 37, line 21 to page 38, line 3.] Thus, one of ordinary skill in the art would be able to ***make and use*** the ***claimed*** invention. The enablement requirement requires no more.

The Examiner appears to be asserting there are some operational "modalities" that would result in the ***dot-like electrodes*** illustrated in Figure 31, which are ***0.5 mm to 1 mm in diameter and about 0.01 mm thick***, forming transmural myocardial lesions. The Examiner appears to have based his opinion, at least in part, on the discussion on page 26 of the present application and its relationship to the Avitall and Imran patents. Specifically, the Examiner appears to be arguing that "size alone is poor determinant of whether an electrode is capable of forming a transmural lesion" because (1) page 25, line 31 to page 26, line 3 of the present specification states that the electrodes 112 and 114, which are much larger than the aforementioned electrodes 604 on the suction device 618, are too small to form a transmural myocardial lesion and (2) the Avitall and Imran patents somehow refute this statement. The Examiner's argument is both irrelevant and incorrect.

Turning first to irrelevance, electrodes 112 and 114 are not the dot-like electrodes that the present application discloses for the purpose of stimulating tissue from the distal end of a suction device. Instead, electrodes 112 and 114 are ***ring and/or tip*** electrodes that are carried on the distal end of a surgical probe. They have no bearing whatsoever on the issue of whether or not the ***dot-like electrodes*** illustrated in Figure 31, which are ***0.5 mm to 1 mm in diameter and about 0.01 mm thick***, are too

small to form a transmural myocardial lesion. In addition, and in view of the fact that the structural and size differences between a ring (or tip) electrode on a surgical probe and a dot-like electrode on a suction device were not recognized by the Examiner, the following "to scale" drawings are provided for the purpose of facilitating a greater level of understanding. A ring electrode with a 2 mm diameter and a 2 mm length is shown below to the left of an electrode with a 1 mm in diameter and a 0.01 mm thickness.



Side Views **End Views**

In order to clarify the issues for appeal, applicant hereby requests that the Examiner clearly explain how the ring and tip electrodes are relevant to the issue of whether or not the dot-like electrodes illustrated in Figure 31 are too small to form a transmural myocardial lesion. In particular, applicant hereby requests that the Examiner explain why, in his opinion, one of skill in the art would expect the dot-like electrode illustrated on the right side of the views above to function in the same manner as the ring electrode illustrated on the left side.

With respect to incorrectness, and in the context of the ***surgical probe*** illustrated in Figure 1, the present application indicates that the flexible lesion forming electrodes 110 carried on the probe shaft are 4-20 mm in length, that the rigid lesion forming electrodes are 2-10 mm, and that "electrodes having lengths of less than about 2 mm do not consistently form the desired continuous lesion patterns." [Page 20, line 28 to page 21, line 5.] The present application also indicates that the stimulation electrodes 112 and 114, which are too small to form transmural myocardial lesions, are 0.5-2.0 mm in length with 0.5-2.0 mm spacing. [Page 25, line 31 to page 26, line 3.] In other words, and although it is not even relevant to claimed suction-related inventions, the present

application indicates that ***2.0 mm in length is the line of demarcation for generally cylindrical (or "ring") electrodes*** that are carried on a shaft.

The Avitall patent discloses the use of electrodes that are 2-4 mm in length for the purpose of forming lesions. However, the only configuration which the Avitall patent indicates was actually tested and shown to form transmural myocardial lesions was a "closely spaced 4 mm" configuration. In other words, the electrodes that Avitall referred to as actually being capable of forming transmural myocardial lesions are ***two (2) to eight (8) times longer*** than the stimulation electrodes 112 and 114 disclosed in the present application. Again, in both cases, the electrodes are ring electrodes and are not even relevant to the issues associated with the claimed apparatus.

With respect to the Imran patent, nothing in the Imran patent even remotely suggests that the electrodes 67 and 68, which are about 1 mm x 1 mm x 0.01 mm in size, are capable of forming a transmural myocardial lesion. More importantly, however, is the fact that at the time the present invention was made, one of even the most pedestrian skill in the art would have known that the tiny mapping electrodes disclosed in the Imran patent are too small to form a transmural myocardial lesion.

Finally, to the extent that the Examiner has taken Official Notice that the stimulation elements which the specification describes as being on a suction device and "too small to form transmural myocardial lesions" can, in fact, form transmural myocardial lesions is some modality (apparently known only to the Examiner), applicant hereby traverses and requests that the Examiner provide an affidavit in accordance with MPEP § 2144.03 and 37 C.F.R. § 1.104(d)(2). The affidavit should set forth the facts upon which the Examiner's conclusions are based. ***In particular, the affidavit should indicate what "modality" would result in a dot-like electrode that is 0.5 mm to 1 mm in diameter and about 0.01 mm thick forming a transmural myocardial lesion***.

C. Conclusion

As illustrated above, the ***claimed*** inventions are clearly enabled. The rejection of claims 7-11, 28, 30-35 and 37-40 under 35 U.S.C. § 112, first paragraph, is, therefore, improper and should be withdrawn.

IV. PRIOR ART REJECTIONS

A. The Rejections

Claims 7, 9-11, 28, 30, 40, 43, 45-47, 49 and 50-52 have been rejected under 35 U.S.C. § 102 as being anticipated by the U.S. Patent No. 4,736,749 to Lundback ("the Lundback '749 patent"). Claims 8, 44 and 48 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Lundback '749 patent and U.S. Patent No. 6,185,442 to Samson ("the Samson '442 patent"). Claims 31-33 and 37-39 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Lundback '749 patent and U.S. Patent No. 4,685,466 to Rau ("the Rau '466 patent"). Claims 34 and 35 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Lundback '749 patent and U.S. Patent No. 7,020,531 to Colliou ("the Colliou '531 patent").

As claims 48-52 have been canceled, the rejections thereof under 35 U.S.C. §§ 102 and 103 have been rendered moot. The rejections of the remaining claims under 35 U.S.C. § 102 and 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Claimed Inventions

Independent claims 7 and 28 call for respective combinations of elements including, *inter alia*, "a suction device" and "a tissue stimulation element that is too small to form a transmural lesion in myocardial tissue on the suction device ***distal surface***."

The respective combinations defined by claims 8-11, 37-40 and 47 include, *inter alia*, the elements recited in claim 7, and the respective combinations defined by claims 30-35 include, *inter alia*, the elements recited in claim 28.

Independent claim 43 calls for a combination of elements including, *inter alia*, "a suction device" and "tissue stimulation means, carried by the suction device ***distal surface***, for stimulating myocardial tissue without forming a transmural lesion in the myocardial tissue." The combinations defined by claims 44-46 include, *inter alia*, the elements recited in claim 43.

C. Discussion

The Lundback '749 patent is directed to a holder for a diagnostic or therapeutic device 30 that is fixed in place by suction force. The holder includes an arrangement 1, an intermediate element 2, and a backpiece 3. Even assuming for the sake of argument that the diagnostic or therapeutic device 30 is too small to form a transmural myocardial lesion, the diagnostic or therapeutic device is not on the distal surface of the holder (i.e. the lip 13).

As the Lundback '749 patent fails to teach or suggest each and every element of the respective combinations recited in independent claims 7, 28 and 43, applicant respectfully submits that claims 7, 9-11, 28, 30, 40, 43, 45-47, 49 and 50-52 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

Turning to claims 8 and 44, applicant respectfully submits that the Samson '442 patent, which has been sited for its purported flexible suction tube teachings, fails to remedy the above-identified teachings in the Lundback '749 patent. Claims 8 and 44 are, therefore, patentable for at least the same reasons as independent claims 7 and 43 and the rejection of claims 8 and 44 under 35 U.S.C. § 103 should also be withdrawn.

With respect to claims 31-33 and 37-39, applicant respectfully submits that the Rau '466 patent, which has been sited for its purported needle electrode teachings, fails to remedy the above-identified teachings in the Lundback '749 patent. Claims 31-33 and 37-39 are, therefore, patentable for at least the same reasons as independent claims 7 and 28

and the rejection of claims 31-33 and 37-39 under 35 U.S.C. § 103 should also be withdrawn.

Turning to claims 34 and 35, applicant respectfully submits that the Colliou '531 patent, which has been sited for its purported stimulation energy teachings, fails to remedy the above-identified teachings in the Lundback '749 patent. Claims 34 and 35 are, therefore, patentable for at least the same reasons as independent claim 28 and the rejection of claims 34 and 35 under 35 U.S.C. § 103 should also be withdrawn.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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Date

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